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|--|-------------|----------------------|---------------------------------|-----------------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/575,875   | 02/01/2007  | Patrick Lewis Blott  | SMNPH.004APC                    | 6850                        |
| 20995 7590 01/23/2009<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 MAIN STREET<br>FOURTEENTH FLOOR<br>IRVINE, CA 92614 |             |                      | EXAMINER<br>TREYGER, ILYA Y     |                             |
|  |             |                      | ART UNIT<br>3761                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>01/23/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/575,875

Applicant(s)

BLOTT ET AL.

Examiner

ILYA Y. TREYGER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/23/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Claims 1-8 are amended.
2. Claim 9 is canceled.
3. Claims 11-23 are new.
4. Claims 1-8 and 10-23 are examined on the merits.

### ***Response to Arguments***

5. The Double Patenting rejection of claim 1 is withdrawn based on Applicant's Remarks, page 11, line 15 to page 12, line 8.
6. Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive:
7. With respect to claim 1, Applicants argue that rejection based on "optimum or workable ranges" based on Applicants' amended Claim 1 would be inappropriate where the prior art does not teach or suggest the desirability of the result achieved.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids within the claimed range, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is from 34 to 42 degrees Celcius (See *The Columbia Electronic Encyclopedia*), which encompasses the claimed range (**MPEP 2144.03 (A-E)**).

***Claim Rejections - 35 USC § 102***

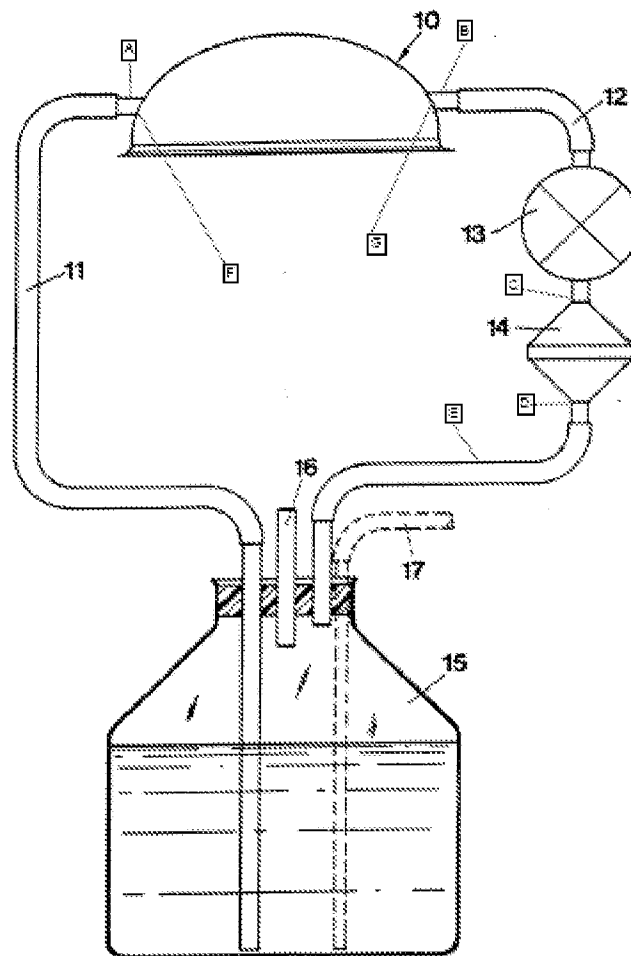
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 14, 19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanbeck (WO 84/01904).

10. In Re claim 19, Swanbeck discloses a device for rinsing and treating wounds comprising: a suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic (p. 2, ln. 33) and consequently fully capable of forming a fluid-tight seal or closure over a wound; the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1); a sterilizing filter (fluid cleansing means) 14 (p. 3, ln. 33; Fig. 1) having an inlet port C (Fig. 1) connected to a fluid offtake tube 12 (Fig. 1) and an outlet port D (Fig. 1) connected to a fluid recirculation tube E (Fig. 1); a fluid reservoir 15 (Fig. 1); a peristaltic pump 13 (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1) which is a device for moving fluid through the wound dressing and cleansing means; an apparatus for supplying thermal energy (p. 4, ln. 3-5). With regard to the bleeding means, it is the position of the Examiner that fluid is supplied via tube 11 from the reservoir 15 and recirculated through the device via tube 12, recirculating the fluid through the flow path.

**FIG 1**

11. In Re claim 21, Swanbeck discloses the apparatus comprising a thermostatically regulated water bath (p. 4, ln. 4,5) which is an corresponds to the heater claimed by applicant.

12. In Re claim 22, In Re claim 3, Swanbeck discloses the apparatus comprising thermostatically regulated water bath (p. 4, ln. 4, 5) fully capable to be heated by the radiative heater, and therefore the reference discloses the equivalent of the radiative heater.

13. In Re claim 23, Swanbeck discloses the apparatus comprising the thermostatically regulated water bath (p. 4, ln. 4,5), which is conductively heated component of the apparatus

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flow path in direct conductive contact with the irrigant and/or wound exudates, and therefore is an equivalent of the conductively heated component.

14. In Re claim 14, Swanbeck discloses the method of treating a wound, comprising the steps of:

providing a conformable wound dressing 10 (Fig. 1) configured to form a relatively fluid-tight seal around at least a portion of a wound (p. 2, ln. 33);

providing an apparatus comprising:

the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1);

pumping fluid through at least the inlet pipe, the wound dressing, and the outlet pipe (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1);

cleansing the fluid that flows out of the wound dressing (p. 3, ln. 33; Fig. 1);

regulating the fluid that flows out of the wound dressing so that a portion of the fluid that flows out of the wound dressing comprising physiologically active components is recirculated back to the dressing after being cleansed and a portion of the fluid that flows out of the wound dressing is bled through a bleed mechanism and is provided to a waste reservoir; and

heating the fluid before the fluid enters the dressing to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the wound dressing and promote wound healing (p. 4, ln. 3-5).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1, 2, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck (WO 84/01904).

19. In Re claim 1, Swanbeck discloses a device for rinsing and treating wounds comprising: a suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic (p. 2, ln. 33) and consequently fully capable of forming a fluid-tight seal or closure over a wound; the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1); a sterilizing filter (fluid cleansing means) 14 (p. 3, ln.

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33; Fig. 1) having an inlet port C (Fig. 1) connected to a fluid offtake tube 12 (Fig. 1) and an outlet port D (Fig. 1) connected to a fluid recirculation tube E (Fig. 1); a fluid reservoir 15 (Fig. 1); a peristaltic pump 13 (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1) which is a device for moving fluid through the wound dressing and cleansing means; an apparatus for supplying thermal energy (p. 4, ln. 3-5). With regard to the bleeding means, it is the position of the Examiner that fluid is supplied via tube 11 from the reservoir 15 and recirculated through the device via tube 12, recirculating the fluid through the flow path.

Swanbeck does not expressly disclose the apparatus maintaining the temperature on the wound in the range between 34 and 40 degree Celsius to optimize the metabolic activities of physiologically active components within the wound dressing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is from 34 to 42 degrees Celcius (See *The Columbia Electronic Encyclopedia*), which encompasses the claimed range (**MPEP 2144.03 (A-E)**).

20. In Re claim 2, Swanbeck discloses the apparatus comprising a thermostatically regulated water bath (p. 4, ln. 4,5) which is an corresponds to the heater claimed by applicant.

21. In Re claim 3, Swanbeck discloses the apparatus comprising thermostatically regulated water bath (p. 4, ln. 4, 5) fully capable to be heated by the radiative heater, and therefore the reference discloses the equivalent of the radiative heater.



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22. In Re claim 4, Swanbeck discloses the apparatus comprising the thermostatically regulated water bath (p. 4, ln. 4,5), which is conductively heated component of the apparatus flow path in direct conductive contact with the irrigant and/or wound exudates, and therefore is an equivalent of the conductively heated component

23. In Re claim 5, Swanbeck discloses the apparatus comprising a sterilizing filter 14 (p. 3, ln. 33; Fig. 1) which is an equivalent of a single-phase cleansing system.

24. In Re claim 10, Swanbeck discloses the method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds (p. 2, ln. 32 – p. 4, ln. 12; Fig. 1).

25. In Re claims 11 and 12, Swanbeck discloses the invention discussed above, but does not expressly disclose the apparatus, wherein the means for supplying thermal energy is configured to supply thermal energy to the fluid in the fluid reservoir or in the inlet pipe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the thermal energy to the fluid in any desired place by relocation the heat conductive element, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

26. In Re claim 13, Swanbeck discloses the apparatus comprising the outlet tube fully capable of being connected to the waste reservoir.

27. In Re claim 15, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the temperature range is between 34 and 40 degrees Celsius.

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The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

28. In Re claim 16, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the fluid in the fluid reservoir is heated to a temperature approximately within the normothermic range.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is a normothermic range (See *The Columbia Electronic Encyclopedia*).

29. In Re claim 17, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the fluid in the fluid reservoir is heated to a temperature slightly above the normothermic range.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to heat the fluid slightly above the normothermic range, since it was known in the art that the fluid loses the temperature while flowing. **(MPEP 2144.03 (A-E)).**

30. In Re claim 20, Swanbeck discloses the invention discussed above, but does not expressly disclose the apparatus, wherein the temperature is maintaining between 34 and 40 degrees Celsius.

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The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

31. Claims 6-8 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Swanbeck (WO 84/01904) in view of Burbank et al. (WO 00/50143). In Re claim 6, Swanbeck discloses the claimed invention discussed above, but does not expressly disclose the apparatus comprising means for fluid cleansing that is a two-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, by the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing (See Abstract, ln. 1-7) which is a two-phase system in which the circulating fluid from the wound or body cavity passes through a means for fluid cleansing and materials deleterious to treatment healing are removed by contacting the spent fluid with a regeneration solution, which comprises another fluid. Therefore the reference discloses the equivalent of the means for fluid cleansing as claimed.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of a treatment apparatus that uses a secondary regeneration or treatment solution to clean or regenerate fluid removed from the treatment area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the apparatus of Burbank to the wound treatment device of Swanbeck in order to provide device with the cleansing apparatus

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that is known in the art, as demonstrated by Burbank, to be suitable to treat a patient with cleaned recirculated fluid.

32. In Re claims 7 and 8, Swanbeck discloses the wound treatment apparatus discussed above, but does not expressly disclose the device comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing (See Abstract, ln. 1-7; P. 18, ln. 4-7).

The reference discloses the equivalent of the means for fluid cleansing as claimed in claims 7 and 8. The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

### ***Conclusion***

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/  
Examiner, Art Unit 3761

/Michele Kidwell/  
Primary Examiner, Art Unit 3761